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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/105,117 06/17/98 VRLIJC

(M) FJ-122

HM12/0716

EXAMINER

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MITRA, R

ART UNIT

PAPER NUMBER

1653

32

DATE MAILED:

07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/105,117	VRLIJC ET AL.
	Examiner Rita Mitra	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 23 April 2001.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

***Status of the Claims***

Applicants' response to office action dated March 23, 2001 (paper #29) filed on April 23, 2001 in paper #30 and a substitute copy of the specification in paper #31 is acknowledged. Upon reviewing the amended copy of the specification and claims, further the inventions require another restriction. Claims 1-48 are presented in the substitute copy for examination.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a process of microbacterial production of amino acids, classified in class 435, subclass 69.1.
- II. Claims 21-26, 29, 31, 32, 34-38, drawn to an export gene having nucleotide sequence encoding an amino acid sequence of an export carrier protein, vectors, and transformed host cells thereof, classified in class 536, subclass 23.7.
- III. Claims 27, 28, 30, 33, 39 and 40, drawn to a regulator gene having nucleotide sequence encoding an amino acid sequence of a regulator protein of export carrier

protein, vectors, and transformed host cells thereof, classified in class 536, subclass 23.7.

IV. Claims 41 and 42, drawn to a transmembrane protein, classified in class 530, subclass 350 and 825.

V. Claims 43-48, drawn to a method of use of an export gene for the production of amino acids in microorganism, classified in class 536, subclass 23.7 and class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the methods for producing amino acids of invention I can be practiced with another materially different product. For example, the methods of invention I are not limited to the nucleic acids encoding the amino acid of export carrier proteins of invention II, but may be practiced by using the membrane proteins of invention IV.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)).

In the instant case the, the nucleic acid of invention III can be used on other, materially distinct processes, such as in hybridization assay, for example. Therefore, the inventions are distinct.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the methods for producing amino acids of invention I can be practiced with another materially different product. For example, the methods of invention I are not limited to the proteins of invention IV, but may be practiced by using the nucleic acids of invention II and III.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the process of invention V involves a step of mutation of the export gene, whereas the starting material of process of invention I is a wild type export gene. Therefore, these inventions are distinct from each other.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of invention II have different functions and effects than the nucleic acids of invention III. Specifically, the nucleic acids of invention II encodes an export protein, whereas the nucleic

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acids of invention III encode a regulatory protein that modulates the expression of export protein of invention II.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, The DNA of invention II and protein of invention IV are distinct inventions because the protein product can be made by other and materially distinct processes such as by synthetic peptide synthesis or purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the mutants of export gene of invention II are used for the methods for producing amino acids of invention V can be practiced with another materially different product. For example, the methods of invention V are not limited to the nucleic acid of invention II, but may be practiced by using the protein of invention IV.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, The DNA of invention III and protein of invention IV are distinct inventions because the protein product can

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be made by other and materially distinct processes such as by synthetic peptide synthesis or purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, the inventions are distinct.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the methods for producing amino acids of invention V can be practiced with another materially different product. For example, the methods of invention V are not limited to the nucleic acid of invention III, but may be practiced by using the nucleic acids of invention II and protein of invention IV.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the methods for producing amino acids of invention V can be practiced with another materially different product. For example, the methods of invention V are not limited to the nucleic acid of invention IV, but may be practiced by using the nucleic acids of invention II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

*Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center

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number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Karen Cochrane Carlson Ph.D*

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

*R. Mitra*

Rita Mitra, Ph.D.  
July 13, 2001